REMARKS

Applicant gratefully acknowledges the telephonic interview with the Examiner conducted on September 11, 2003. Applicant has attempted to address the issues raised by the Examiner in the interview with this response.

Applicant requests reconsideration of the application in view of the following remarks. Claims 24 and 25 have been amended. New claims 26-38 have been added. Claims 24, 25, 26, 35 and 38 are independent claims. No new matter has been added by the amendments herein.

INFORMATION DISCLOSURE STATEMENT

Applicant gratefully acknowledges the Examiner's consideration of the references sent with the Supplemental IDS filed on May 14, 2003.

DRAWING OBJECTION

The Examiner objected to the drawings as failing to comply with 37 C.F.R. 1.84 (p)(4). Specifically, the Examiner asserted that reference numerals "58" and "54" were both used to designate valleys in FIG. 8. In the telephonic interview on September 11, 2003, the Examiner indicated that the proposed drawings filed on May 14, 2003 were sufficient to overcome the objection and would be entered.

CLAIM OBJECTIONS

The Examiner objected to the claims as not in accordance with 37 C.F.R. 1.126. Specifically, the examiner indicated that claims 22 and 23, presented in the supplemental response to the March 18, 2003 Office action should be renumbered as claims 24 and 25 respectively. In the telephone interview on September 11, 2003, the Examiner indicated that no formal amendment was required to renumber the claims as the Examiner had already renumbered them. It is respectfully noted that previous claims 22 and 23 have been renumbered as claims 24 and 25 herein.

35 U.S.C. § 102 REJECTIONS

The Examiner rejected claims 24 and 25 under 35 U.S.C. §102(e) as being anticipated by Klein, U.S. Patent No. 5,593,442. Applicant respectfully disagrees with the Examiner's interpretation of Klein and traverses this rejection.

In the Office action, the Examiner attached a copy of Klein Fig. 4B. The Examiner highlighted the portions of the stent illustrated in Fig. 4B that he asserted as the "reinforcing member," "interconnecting member" and "cylindrical [elements]" recited in independent claims 24 and 25 of the present invention.

It is respectfully noted that anticipation of claims using a drawing requires that "the picture must show all the claimed structural features and how they are put together" and "[t]he drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art." M.P.E.P. § 2125. Furthermore, anticipation of a claim under 35 U.S.C. § 102 (a), (b) and (e) requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," that "[t]he identical invention must be shown in as complete detail as is contained in the ... claim" and "[t]he elements must be arranged as required by the claim." M.P.E.P. § 2131.

In the telephonic interview on September 11, 2003 it was respectfully noted that Klein Fig. 4B is a view of the stent illustrated in Fig. 4A in the radially expanded condition. See Klein at col. 3, ll. 27-31. It was further respectfully noted in the interview that the portion of the Klein stent which the Examiner asserts as the "reinforcing member" is actually a portion of one of the rectangular boxes that comprise the box structures 46 and the portion of the Klein stent that the Examiner asserts as the "cylindrical [element]" is actually the other portion of the same rectangular box combined with two of the tabs 48 which join adjacent rectangular boxes. See Klein at col. 6, ll. 43-50 and Figs. 3, 4A and 4B.

It was respectfully submitted in the interview that nowhere in Klein is there support for the Examiner's interpretation of a portion of the rectangular boxes as a "reinforcing member" and a portion of the same rectangular box as the "cylindrical

[element]." In fact, the only disclosure in Klein of a "cylindrical element" is the cylindrical serpentine ring 49 which is disclosed as part of the articulation structures 44, 45 and which is comprised of linear elements 51a, b, and c. See Klein at col. 6, ll. 50-54 and Figs. 4A and 4B. It was further respectfully noted in the interview, and the Examiner apparently agreed, that there is no "reinforcing member" between the linear elements 51a, b, and c that comprise the cylindrical serpentine ring disclosed in Klein.

It was respectfully submitted in the interview that nowhere in Klein is it taught or disclosed that the portion of the rectangular boxes that the Examiner asserts as a "reinforcing member" is "configured to limit the radial expansion" of the portion of the rectangular boxes that the Examiner interprets as the "cylindrical [element]" as required by independent claims 24 and 25 of the present invention. It was further respectfully submitted in the interview that when the Klein stent structure 40 is expanded, the rectangular boxes bend at the tabs and there is no support in Klein for the interpretation that any portion of the rectangular boxes is configured to limit the radial expansion of any other portion of the same rectangular boxes as is required by the Examiner's interpretation. See Klein Figs. 4A and 4B.

It is respectfully submitted that Fig. 4B of Klein would not be interpreted, in view of the disclosure therein, by one of ordinary skill in the art as disclosing the elements asserted by the Examiner and, therefore, that Fig. 4B does not clearly show all the claimed structural features recited in independent claims 24 and 25. It is further respectfully submitted that one of ordinary skill in the art would not interpret Klein as disclosing "reinforcing members" that are "configured to limit the radial expansion of the cylindrical elements." Moreover, it is respectfully submitted that Klein does not disclose every element recited in independent claims 24 and 25 with the requisite detail nor does Klein disclose the elements arranged as required by the claims and, therefore, that Klein does not meet the requirements for anticipation under 35 U.S.C. § 102(e).

It is respectfully asserted that the Examiner's interpretation of Fig. 4B of Klein as disclosing "cylindrical [elements]," "interconnecting members" and "reinforcement members" is improper and that independent claims 24 and 25 are not anticipated.

Although Applicant believes that independent claims 24 and 25 are allowable over Klein, the claims have been amended to further distinguish over the Klein reference. Claim 24 has been amended to recite that the circumferential width of the reinforcing member is smaller than the width of the peak or valley it extends across when the stent is in the contracted condition. Claim 25 has been amended to recite that reinforcing members extend across at least one peak or one valley in each of the plurality of cylindrical elements. Support for the amendments is found in the specification in Figs. 8 and 9 and at page 10 as amended at the suggestion of the Examiner in the interview.

It is respectfully noted that the portion of the Klein stent the Examiner asserts as the "reinforcing member" has a circumferential width that is the same as the width of the peak or valley it extends across when the Klein stent is in the contracted condition. See Klein Fig. 4A. It is respectfully submitted that nowhere in Klein is a stent disclosed in which the circumferential width of a reinforcing member is smaller than the width of the peak or valley it extends across when the stent is in the contracted condition. Therefore, it is respectfully asserted that independent claim 24 is allowable over the cited reference.

As noted previously, the Examiner apparently agreed in the interview that there is no "reinforcing member" between the linear elements 51a, b, and c that comprise the cylindrical serpentine ring of the articulation structure disclosed in Klein. It is respectfully submitted that nowhere in Klein is a cylindrical serpentine ring disclosed that has a "reinforcing member" between the linear elements 51a, b, and c. Therefore, it is respectfully asserted that Klein does not teach or disclose reinforcing members which extend across at least one peak or one valley in each of the plurality of cylindrical elements and independent claim 25 is allowable over the cited reference.

The Examiner rejected claim 24 under 35 U.S.C. § 102(e) as being anticipated by Killion, U.S. Patent No. 5,868,781. Applicant respectfully traverses this rejection.

Applicants have attached herewith a copy of the Declaration pursuant to 37 C.F.R. § 1.131 to swear behind the Killion `781 patent that was previously filed on June 16, 2003, as discussed during the September 11, 2003 telephone interview with the Examiner. Applicant respectfully requests that the § 102(e) rejection be withdrawn.

The Examiner rejected claims 24 and 25 under 35 U.S.C. §102(b) as being anticipated by Palmaz, U.S. Patent No. 5,102,417. Applicant respectfully disagrees with the Examiner's interpretation of Palmaz and traverses this rejection.

In the Office action, the Examiner attached a copy of Palmaz Figs. 7 and 10. The Examiner highlighted the portions of the stent illustrated in Fig. 10 that he asserted as the "reinforcing member," "interconnecting member" and "cylindrical [elements]" recited in independent claims 24 and 25 of the present invention.

In the telephonic interview on September 11, 2003 it was respectfully noted that Palmaz Fig. 10 is a view of the stent illustrated in Fig. 7 in the expanded condition and that Fig. 7 is a view of a stent comprised of the portions illustrated in Figs. 1A and 1B. See Palmaz at col. 6, ll. 8-9, and col. 11, ll. 48-51. It was further respectfully noted in the interview that the portion of the Palmaz stent that the Examiner asserts as the "reinforcing member" is actually a portion of one of the elongate members 75 that extend between first and second ends 72, 73 of tubular member 71 and the portion of the Palmaz stent that the Examiner asserts as the "cylindrical [element]" is actually the other portion of the same elongate member, with adjacent elongate members separated by connecting members 77. See Palmaz at col. 7, ll. 25-37 and Figs. 1A, 1B, 7 and 10. It was respectfully submitted in the interview that nowhere in Palmaz is there support for the Examiner's interpretation of a portion of the elongate member as a "reinforcing member" and a portion of the same elongate member as the "cylindrical [element]."

It was respectfully submitted in the interview that nowhere in Palmaz is it taught or disclosed that the portion of the elongate member that the Examiner interprets as the "reinforcing member" is "configured to limit the radial expansion" of the portion of the elongate member that the Examiner interprets as the "cylindrical [element]" as required by independent claims 24 and 25 of the present invention. It was further respectfully submitted in the interview that when the Palmaz stent structure 70 is expanded, the elongate members bend at the connecting members, or the point where the Examiner delineates between the asserted "reinforcing member" and "cylindrical [element]" and there is no support in Palmaz for the interpretation that any portion of the elongate

members are configured to limit the radial expansion of any other portion of the same elongate members as required by the Examiner's interpretation. See Palmaz at col. 8, ll. 21-50 and Figs. 1A, 1B, 7 and 10.

It is respectfully submitted that Fig. 10 of Palmaz would not be interpreted, in view of the disclosure therein, by one of ordinary skill in the art as disclosing the elements asserted by the Examiner and, therefore, that Fig. 10 does not clearly show all the claimed structural features recited in independent claims 24 and 25. It is further respectfully submitted that one of ordinary skill in the art would not interpret Palmaz as disclosing "reinforcing members" that are "configured to limit the radial expansion of the cylindrical elements." Moreover, it is respectfully submitted that Palmaz does not disclose every element recited in independent claims 24 and 25 with the requisite detail nor does Palmaz disclose the elements arranged as required by the claims and, therefore, that Palmaz does not meet the requirements for anticipation under 35 U.S.C. § 102(b).

It is respectfully asserted that the Examiner's interpretation of Fig. 10 of Palmaz as disclosing "cylindrical [elements]," "interconnecting members" and "reinforcing members" is improper and that independent claims 24 and 25 are not anticipated.

Although Applicant believes that independent claims 24 and 25 are allowable over Palmaz, the claims have been amended to further distinguish over the Palmaz reference. As noted previously, claim 24 has been amended to recite that the circumferential width of the reinforcing member is smaller than the width of the peak or valley it extends across when the stent is in the contracted condition. Claim 25 has been amended to recite that the interconnecting member is essentially parallel to the longitudinal stent axis when the stent is in the contracted condition. Support for the amendment is found in the specification in Figs. 8 and 9 and at page 10 as amended at the suggestion of the Examiner in the interview.

It is respectfully noted that the portion of the Palmaz stent the Examiner asserts as the "reinforcing member" has a circumferential width that is the same as the width of the peak or valley it extends across when the Palmaz stent is in the contracted condition; See Palmaz Fig. 7. It is respectfully submitted that nowhere in Palmaz is a stent disclosed in

which the circumferential width of a reinforcing member is smaller than the width of the peak or valley it extends across when the stent is in the contracted condition. Therefore, it is respectfully asserted that independent claim 24 is allowable over the cited reference.

It was respectfully noted in the interview, and the Examiner apparently agreed, that the connector members 100 which connect adjacent prostheses 70, and which the Examiner asserts as the "interconnecting members" recited in claim 25, are not essentially parallel to the longitudinal stent axis when the stent is in the contracted condition. In fact, Palmaz teaches that the connector members are "in a non-parallel relationship with respect to the longitudinal axis of adjacent grafts or prostheses 70." Palmaz at col. 12, ll. 7-10. Therefore, it is respectfully asserted that independent claim 25 is allowable over the cited reference.

35 U.S.C. § 103 REJECTIONS

The Examiner rejected claim 25 under 35 U.S.C. §103(a) as being unpatentable over Killion in view of Palmaz. Applicant respectfully traverses this rejection.

Since the Applicant has sworn-behind Killion, that reference is not available to the Examiner. As asserted previously, claim 25 is allowable over Palmaz. Therefore, it is respectfully requested that the rejection be withdrawn.

NEW CLAIMS

New claims 26-38 have been added. It is believed that the new claims which recite limitations similar to claims 24 and 25 discussed herein, are allowable over the cited references and in condition for allowance.

CONCLUSION

Applicant has attempted to respond to each and every objection and rejection set forth in the outstanding Office action. In view of the above remarks, Applicant respectfully requests that the application be reconsidered, the claims allowed and the application passed to issue.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____

Richard C. Salfelder
Registration No. 51,127

RCS:gbr

Enclosures: Copy of Declaration of Richard T. Allen and Daniel L. Cox
Copy of Exhibit A

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25713.1

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 16, 2003.

Richard C. Salfelder, Reg. No. 51,127

OIPE JC37 OCT 30 2003 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Richard T. Allen et al.

Serial No. 09/848,819

Filed: May 3, 2001

Continuation of U.S. Serial No. 08/881,059

For: STENT WITH REINFORCED STRUTS AND BIMODAL DEPLOYMENT

Examiner: W. Matthews

Group Art Unit: 3738

Client ID/Matter No. ACS 57527 (1201C)

Date: June 16, 2003

DECLARATION UNDER 37 C.F.R. § 1.131

We, RICHARD T. ALLEN and DANIEL L. COX, declare as follows:

1. We are co-inventors of the subject matter of the above-identified application.

2. We have been informed that U.S. Patent No. 5,868,781 to Killion, filed October 22, 1996 has been cited as a prior art reference against the present application.

3. We invented the claimed subject matter prior to October 22, 1996. Attached as Exhibit A is the invention disclosure form dated prior to October 22, 1996 which includes the drawings that depict the claimed stent and which is the subject matter of the pending claims. The Invention Disclosure Form was signed by us and by a witness

COPY

prior to October 22, 1996. The dates on the Invention Disclosure Form have been redacted.

4. We worked diligently on the development of the claimed invention from the time just before October 22, 1996 until the filing of the present application on May 3, 2001.

5. All of the work relating to the claimed subject matter was conducted in the United States at Santa Clara, California.

As the persons signing below, we hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with full knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title XVIII of the United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

DATE: June 5, 2003

Richard T. Allen
RICHARD T. ALLEN

DATE: June 5, 2003

Daniel L. Cox
DANIEL L. COX

15283.1

CONFIDENTIAL & PRIVILEGED

ADVANCED CARDIOVASCULAR SYSTEMS, INC.

INVENTION DISCLOSURE FORM

To: Legal Department

cc: Motasim Sirhan

For Legal Department Use Only

Docket No.:
Date Assigned:

Submitter: Daniel Cox and Richard Allen

This is a form for disclosing ideas and inventions to the ACS Legal Department for patent consideration. This form may be used before experimental work has been done. While some of the requested information may not be available at this time, include as much information as you can about the invention. Attach additional sheets if necessary, and sign and date each sheet. Additional information will be requested later.

1. DESCRIPTIVE TITLE OF THE INVENTION
Stent with Reinforced Struts and Bimodal Deployment

2. DESCRIPTION AND USE - (a) Describe the invention in as much detail as possible, and include a description of a working prototype, if any. Write your description using reference numerals placed on a drawing. Point out and explain relationship with associated equipment. (b) How is the invention used? (c) How does it relate to present or potential commercial products of ACS or others? (d) State the significance of the invention, and any problems it is intended to solve. Please supplement when possible by attaching sketches, engineering drawings, pages from lab books, photographs, and the like.

The devices described are endovascular stents which would be used in a manner similar to the current ACS Multilink. All of the devices described could be cut from a tube using a laser as a convenient manufacturing method.

COPY

EXHIBIT A

The area of peak stress in most zigzag type stent designs is at or near the apex of the curve, 1, at the ends of the zigzags (Figure 1). The invention is a method for reinforcing this area with an additional member, 2, which is attached to each side of the the zigzags away from the apex of the main curve, 1. This member can be constructed in a variety of ways, some examples of which are shown in Figure 1. The strut width of the main curve, 1, in relation to the width and geometry of the reinforcing member, 2, would be experimentally determined for each configuration to distribute the stress between the two members. This would probably vary with the material chosen for the stent.

where?

A complete stent could be constructed from this geometry in a variety of ways. Two examples are drawn in Figures 2 and 3. The stent in Figure 2 uses the reinforcing geometry of Figure 1C as the base pattern. This pattern connects the reinforcing member, 3, to the next ring at 4. When deployed this stent will probably shorten somewhat. The stent in Figure 3 is based on the geometry in Figure 1J. This base patterns are connected similar to that of the ACS Multilink.

The length and width of the reinforcing member could be chosen to create a bimodal deployment. This is illustrated in Figure 4 based on the stent in Figure 3. The first mode is shown in Figure 4A in which the reinforcing member, 5, straightens and locks into position. The reinforcing member in this configuration provides substantial strength and stiffness to the stent. As the stent is expanded further, the strut, 6, bends at point 7 until it is aligned with the circumference of the stent as shown in Figure 4B. At this point the stent is fully deployed to its maximum diameter. Note that the reinforcing member and stent could be made to deploy without 2 distinct modes. This behavior is controlled by the force required to bend the strut, 6, at point 7, compared to the force require to bend and open the reinforcing member. This can be controlled by the relative widths and lengths of the various members.

3. PROJECTED GENERIC SCOPE - Describe the invention in terms of the broadest generic scope which you expect will be operable (e.g. if a machine or article, describe alternate type and sizes of materials for construction, etc.; if a process, describe alternate manufacturing conditions, etc.).

Should apply to any of the standard stent materials like stainless steel, NiTi, tantalum, Pt/Ir, etc. It should also work in any appropriate diameter tubular structure in the body which may benefit from a stent. The designs shown are all balloon expandable by a standard angioplasty catheter.

Dan & Cy

Richard Allen

4. REFERENCES - (a) Has a literature search been made? (b) List and, if possible, attach copies of all literature, publications, patents, and patent applications of which you are aware relating to the invention. See section in Guidelines for Completing Invention Disclosure Form concerning obligation of disclosure.

No literature search has been done.

5. DISCLOSURE OR USE - (a) Is the invention known to anyone outside of ACS ? (b) Has the invention been used outside ACS ? (c) What is the current stage of development of the invention ? (d) Are there plans to disclose or use the invention outside of ACS ?

The inventions have not been shown to anyone outside ACS. The current designs are in the proof of concept phase and no prototypes have been produced yet. There are no current plans to disclose this information.

Submitters Daniel L. Cox
Print and Sign

Date

Richard Allen Rutledge

Read and Understood the completed Invention Disclosure Form (not a Submitter)

Richard J Rapoza
Print and Sign

Date

PLEASE PRINT NAME OF DIRECTOR AND MANAGER

Director Motasim Sirhan Manager Richard Rapoza

Director _____ Manager _____

Director _____ Manager _____

Figure 1